order and, consequently, a federalism summary impact statement is not required.

XII. References

The following reference marked with an asterisk (*) is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* References without asterisks are not available for electronic viewing because they have copyright restriction, or they are available as published articles and books, but these references are available for viewing by interested persons at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Larrañaga, M.D., R.J. Lewis Sr., and R.A. Lewis, *Hawley's Condensed Chemical Dictionary,* 16th ed., New Jersey: Wiley (2016), s.vv. ''peptide,'' ''polypeptide,'' ''protein.''
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3. J. Stenesh, *Dictionary of Biochemistry and Molecular Biology,* 2nd ed., New Jersey: Wiley (1989), s.vv. ''polypeptide,'' ''protein.''
4. *The American Heritage Science Dictionary,* New York: Houghton Mifflin (2005), s.vv. ''peptide,'' ''protein.''
5. Creighton, T.E., *Encyclopedia of Molecular Biology,* New Jersey: Wiley (1999), s.vv. ''peptide,'' ''polypeptide.''
6. Newman, W.A., *Dorland's Illustrated Medical Dictionary,* 28th ed., Pennsylvania: W.B. Saunders Co. (1994), s.vv. ''peptide,'' ''polypeptide.''
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8. Voet, D. and J. Voet, *Biochemistry,* 3rd ed., New Jersey: Wiley (2004), p. 68.
9. Pollard, T., W. Earnshaw, et al., *Cell Biology,* New York: Elsevier (2002), p. 21.
10. Lodish, H., A. Berk, C.A. Kaiser, et al., *Molecular Cell Biology,* 6th ed., London, U.K., W.H. Freeman (2007), p. 66.
11. Alberts, B., A. Johnson, J. Lewis, et al., *Molecular Biology of the Cell,* 4th ed., New York: Garland Science (2002), pp. 129, 135.
* 12. Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Definition of the Term ''Biological Product''; Proposed Rule, 2018, available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 600 be amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 356c, 356e, 360, 360i, 371, 374, 379k–1; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

■ 2. Amend § 600.3 by revising paragraph (h) introductory text and by adding paragraphs (h)(6) and (7) to read as follows:

§ 600.3 Definitions.

* * * * *

(h) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings:

* * * * *

(6) A protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

(7) A chemically synthesized polypeptide is any alpha amino acid polymer that is made entirely by chemical synthesis and is greater than 40 amino acids but less than 100 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(7) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

* * * * *

Dated: December 6, 2018.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2018–26840 Filed 12–11–18; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2018–0008; Notice No. 177]

RIN 1513–AC40

Proposed Establishment of the West Sonoma Coast Viticultural Area

Correction

In proposed rule document 2018–26321 beginning on page 62750 in the issue of Thursday, December 6, 2018, make the following correction:

On page 62751, in the first column, in the **DATES** heading, the second line, ''January 7, 2018'' should read ''February 4, 2018''.

[FR Doc. C1–2018–26321 Filed 12–11–18; 8:45 am]

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